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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/089,871
Filing Date: June 04, 1998
Appellant(s): BARENDSE ET AL.

Roberte M. D. Makowski
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/12/2009 appealing from the Office action mailed 9/30/2008.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

While Appellant has cited Appeal No. 2006-0201 as an appeal that may have a bearing on the current appeal, the Examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6120811	Ghani	9-2000
4106991	Markussen et al.	8-1978
WO 95/28850	Nielsen et al.	11-1995
GB 2-139-868A	Haarasilta	11-1984

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(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-19, 21-22, 24, 26-28, 31-35, 41-46, 48, 50-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18-19 (claims 21-22, 24, 26-28, 31-35, 41-46, 48, 50-52 dependent thereon) are indefinite in the recitation of "increased pelleting stability" for the following reasons. The term is unclear and confusing in the absence of a reference point to compare pelleting stability (i.e., increased with respect to what).

These claims were also found indefinite on the ground that the term "pelleting stability" have two reasonable interpretations: one that refers to the structural stability of the pellet under different conditions (e.g., temperature, pressure, pH, etc.) and another that refers to the stability of the enzyme after pelleting. Since the specification does not provide a specific definition for the term, the term was found unclear as one could not determine which interpretation should be used. Upon further consideration and in view of appellant's assertions indicating that the term should be interpreted as related to the stability of the enzyme after pelleting, this ground of rejection is hereby withdrawn. The claims, however, remain indefinite for the reasons stated above and also indicated in the Office action mailed on 7/27/2007, page 3, item 4.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-19, 21-22, 24, 26-28, 31-35, 41-46, 48, 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996) and further in view of Haarasilta (GB 2-139868A, 1984).

Nielsen et al. teach an animal feed additive comprising one or more phytases wherein said additive is a granulated product that can be readily mix with feed (page 10, lines 16-18), and wherein the amount of phytase activity in the animal feed additive (granulate) is in the range of 200 to 50000 FYT per gram of total composition, including a specific reference to a phytase activity of 6000 FYT per gram of total composition (page 11, lines 27-30-page 12, line 2). FYT as indicated by Nielsen et al. is the abbreviation they use for phytase unit (page 12, lines 18-21) and is the same as FTU as recited in the claims (see footnote on page 15 of the brief). Nielsen et al. teach that the preferred phytases are *Aspergillus* phytases including *Aspergillus ficum* phytases (page 5, lines 25-29). It is noted that the working examples provided in the specification were all carried out with an *Aspergillus ficum* phytase. Furthermore, Nielsen et al. teach that the phytase-containing granulated feed additive comprises additional glucosidase enzymes such as a xylanase, a xylan-endo-1,3- β -xylosidase (EC 3.2.1.32; also called endo 1,3- β -xylanase) and endo-1,6- β -glucanase (EC 3.2.1.75) (page 11, lines 5-19). In addition, Nielsen et al. teach (1) the size of the granulates is compatible with that of the feed, (2) the granulates can be coated or uncoated (page 10, lines 19-21), and (3) pelleting or extrusion of the feed (page 10, lines 25-26).

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Nielsen et al. do not specifically teach extrusion of the granulated feed additive as recited in claim 18, or a phytase-containing granulate comprising a divalent cation, a non-fibrous solid carrier comprising at least 15% (w/w) of starch, a gel-forming compound, or an edible oil.

Ghani teaches an enzyme granulate and compositions thereof, wherein a solid carrier can be a starch-containing compound such as corn flour, ground corn cobs, soy flour as well as alpha cellulose, regular or spray dried lactose, maltodextrins, and corn syrup solids (column 2, lines 25-34). Corn syrup would not have fibers. Corn flour and ground corn cobs would have starch. Ghani discloses a carrier comprising corn syrup with soy flour, which is further coated with Miragel 463 (hydrolyzed starch) (column 6, lines 43-50, Example 5). Ghani also teaches enzyme granulates which comprise hydrolyzed starches and gums (column 2, lines 35-52) as well as low viscosity algin and algin blends (column 2, lines 53-57; gel forming compounds). Ghani teaches that starch with corn syrup is preferred because the combination provides a matrix for fusing the carrier particles together to build the particle size, and the corn syrup which is hydrophilic, helps disperse and breakdown the granule in the presence of an aqueous environment (column 2, lines 45-52). In addition, Ghani teaches that the amount of enzyme to be used in a granule can be adjusted according to the activity desired for the finished product (column 3, lines 45-47). Ghani does not teach an enzyme granulate where the enzyme is a phytase.

Haarasilta teaches a fodder in granulated form which comprises soy oil (page 2, lines 13-15) and teaches that to aid in the formation of stable granules, inorganic salts can be added which contain divalent cations such as Ca^{2+} or alkaline earth metal cations (page 2, lines 19-21). Haarasilta also teach extrusion as a method to produce the granules (page 1, lines 42-46). Haarasilta does not teach a phytase granulate.

Claims 18, 45-46, 48, 50-52 are directed in part to an *Aspergillus* phytase-containing granulate comprising at least 6000 phytase units (FTU) per gram, wherein said granulate is prepared from an aqueous liquid comprising at least 14000 FTU per gram of aqueous liquid by extrusion, wherein said granulate contains a carrier comprising at least 15% (w/w) of starch, and wherein the granulate also

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comprises edible oil, an endo-xylanase, and a β -glucanase. Claims 19, 21-22, 24, 26-28 are directed in part to an *Aspergillus* phytase-containing granulate comprising at least 6000 phytase units (FTU) per gram, wherein said granulate is prepared from an aqueous liquid comprising at least 14000 FTU per gram of aqueous liquid, wherein said granulate contains a carrier comprising at least 15% (w/w) of starch, and wherein the granulates also comprise a divalent cation, edible oil, an endo-xylanase, and a β -glucanase. Claims 31-35, 41-44 are directed in part to a composition comprising the *Aspergillus* phytase-containing granulate described above with regard to claims 18-19, 21, 24, 26-28, 45, 48, 50-52, wherein said composition is an edible animal feed, or wherein the composition also comprises pellets that comprise one or more feed substances.

The limitation "high activity" recited in claim 18 has been considered redundant in view of the fact that the activity has been numerically defined (i.e., at least 6000 FTU per gram). Limitations with regard to the phytase concentration of the solution used to make the granulates (i.e., 14000 FTU per gram of aqueous liquid) or the method used to make the granulate (i.e., extrusion) have been given little or no patentable weight in view of the fact that these are product-by-process limitations which are not deemed to have any effect on the structural/functional characteristics of a granulate as claimed, which after being manufactured, is required to have a phytase activity of at least 6000 FTU per gram, regardless of the phytase concentration in the solution used to make the granulate or the mechanical method by which the granulate is made.

With regard to the "increased pelleting stability" limitation, it is noted that even if this term were to be found definite, as asserted by appellant, the specification as well as appellant, have indicated that the higher the phytase activity in the granulate used in the pelleting process, the higher the reduction in loss of phytase activity. Thus, as taught by the specification, **the only characteristic of the granulate which has been taught by the specification as being associated with pelleting stability is the phytase activity of the granulate.** The specification states on page 8, lines 23-28,

“The mechanical processing used in the present invention for making the mixture of the phytase-containing liquid and the solid carrier into granules (in other words granulating) can employ **known** techniques frequently used in food, feed and enzyme formulation processes. This can comprise expansion, **extrusion**, spheronisation, pelleting, high shear granulation, drum granulation, fluid bed agglomeration or a combination thereof.” (emphasis added).

Thus, it is clear to one of ordinary skill in the art from the teaching of the specification that **Appellant (1) does not consider the mechanical process by which the granulate is made as a contributing factor in the observed enhancement of pelleting stability, and (2) admits on the record that extrusion is a well known technique for making granulates.** Thus, at a minimum, the specification clearly teaches that if the granulate is made by expansion, extrusion, spheronisation, pelleting, high shear granulation, drum granulation, fluid bed agglomeration or a combination of any of these techniques, the granulate is expected to have the desired pelleting stability so long as the phytase activity in said granulate is high.

Furthermore, the specification states on page 7, lines 7-22,

“Starch is the preferred carbohydrate polymer. **Other suitable glucose-containing polymers** that can be used instead of, or in addition to starch, include α -glucans, β -glucans, pectin (such as proto-pectin), and glycogen. Derivatives of these carbohydrate polymers, such as ethers and/or esters, thereof are also contemplated, although gelatinised starch is often avoided. Suitably the carbohydrate polymer is water-insoluble.

In the examples described herein corn-, potato- and rice-starch is used. However, starch obtained from **other** (e.g., plant, such as vegetable or crop) sources such as tapioca, cassava,

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wheat, maize, sago, rye, oat, barley, yam, sorghum, or arrowroot is equally applicable. Similarly both native or modified (e.g., dextrin) types of starch can be used in the invention. Preferably the carbohydrate (e.g., starch) contains little or no protein, e.g., less than about 5% (w/w), such as less than about 2% (w/w) preferably less than about 1% (w/w). Even more desirably the carbohydrate contains from about 0.005% (w/w) to about 1% (w/w).

At least about **15%** (w/w) of the solid carrier can comprise the carbohydrate polymer (such as starch). Preferably, however, at least about 30% (w/w) of the solid carrier comprises the carbohydrate, optimally at least about 40% (w/w). Advantageously the major component of the solid carrier is the carbohydrate (e.g., starch), for example more than about 50% (w/w), preferably at least about 60% (w/w), suitably at least about 70% (w/w), and optimally at least about 80% (w/w). Thus, desirably the carbohydrate comprises from about 40% to about **100%** (w/w), particularly from about 70% to about 90% (w/w) of the solid carrier.” (emphasis added).

Thus, it is clear from the specification that which glucose-containing polymer, which type of starch is used, or how much % (w/w) of carbohydrate-containing polymer is used to make the granulate is not a factor in the observed enhancement of pelleting stability, since the specification teaches that **starch can be replaced with other glucose-containing polymers, any starch can be used, and the % (w/w) of the carbohydrate polymer that can be used in making the granulates encompasses a very broad range (15%-100%)**. In view of the teachings of the specification, one of skill in the art would reasonably conclude that **since the only characteristic taught as being associated with pelleting stability is the phytase activity content of the granulate itself, any granulate that has the phytase activity indicated as being optimal for pelleting stability would inherently have the desired pelleting stability**.

It is important to note that the “non-fibrous” limitation recited in claims 18 and 19 cannot be interpreted as “lacking fiber” in view of the fact that the carrier is required to have at least 15% (w/w) of

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starch and as known in the art, and also shown by the Examiner in the starch content table provided with the Advisory action mailed on 8/15/2006, starch contains dietary fiber (see item 13 of the PTO-303 form submitted with that action). Thus, a carrier containing starch cannot be a carrier that lacks fiber, i.e., non fibrous. A portion of the table submitted by the Examiner with the Office action of 8/15/2006 containing the relevant information is reproduced below.

Cornstarch

Refuse: 0%

Scientific Name:

NDB No: 20027 (Nutrient values and weights are for edible portion)

Nutrient	Units	Value per 100 grams	Number of Data Points	Std. Error	1.00 X 1 cup ----- 128g
Proximates					
Water	g	8.32	5	0.705	10.65
Energy	kcal	381	0	0	488
Energy	kJ	1594	0	0	2040
Protein	g	0.26	5	0.028	0.33
Total lipid (fat)	g	0.05	3	0.025	0.06
Ash	g	0.09	4	0.003	0.12
Carbohydrate, by difference	g	91.27	0	0	116.83
Fiber, total dietary	g	0.9	0	0	1.2
Sugars, total	g	0.00	1	0	0.00
Minerals					
Calcium, Ca	mg	2	7	0.534	3
Iron, Fe	mg	0.47	6	0.125	0.60
Magnesium, Mg	mg	3	7	0.124	4
Phosphorus, P	mg	13	3	0.588	17
Potassium, K	mg	3	7	0.398	4
Sodium, Na	mg	9	4	2.545	12
Zinc, Zn	mg	0.06	6	0.018	0.08

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make an *Aspergillus* phytase-containing granulate having at least 6000 FTU per gram which can be used as additive in animal feed, as taught by Nielsen et al., wherein the granulate is made using a carrier that comprises starch, as taught by Ghani, wherein said granulate is made using a phytase solution having a phytase concentration of more than 14000 FTU per gram of solution, and wherein said granulate further

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comprises (1) an endo-xylanase and/or β -glucanase as taught by Nielsen et al, (2) at least one divalent cation as taught by Haarasilta, (3) an edible oil taught by Haarasilta, and/or (4) a gel-forming compound as taught by Ghani, wherein the granulate is made by extrusion, as taught by Haarasilta. As indicated above a limitation regarding the phytase concentration of the liquid solution used to make the granulate is a product-by-process limitation which has no effect on the structural/functional characteristics of the claimed granulate because all that matters is that the starting material has enough phytase activity so that the granulate has the recited phytase activity, i.e., at least 6000 FTU per gram, after its manufacture. With regard to the claimed composition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the *Aspergillus* phytase-containing granulate described above to an animal feed composition or to the pelleted animal feed taught by Nielsen et al.

A person of ordinary skill in the art is motivated to (1) make an *Aspergillus* phytase-containing granulate using a carrier that contains, for example, corn syrup (non fibrous) and starch as well as a divalent cation for the benefit of adding nutritional value to the granulate and also due to the fact that phytases aid in the digestion of phytate-containing substances as taught by Nielsen et al. (page 2, lines 7-21), (2) use extrusion to prepare the granules as this method is well known and commonly used in industry for granulate manufacture, as evidenced by Nielsen et al. and Haarasilta, (3) add a gel-forming compound for the benefit of solidifying the granules and maintaining moisture and softness, (4) add an edible oil to the phytase granulate to facilitate binding of hydrophobic compounds which may be part of the granulate, to add nutritional value to the granulate, or as a lubricant to avoid adhesion in the extruder, (5) add an endo-xylanase and/or β -glucanase since these are hydrolytic enzymes which would help in the digestion of complex carbohydrates which might be present in the feed, as taught by Nielsen et al., and (6) add Ca^{2+} to increase the nutritional value of the granulate and also in view of the teachings of Haarasilta. With regard to the limitation requiring the carrier to have at least 15% (w/w) of starch, it is noted that the motivation to use a particular % (w/w) of starch derives from the teachings of Ghani

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regarding the use of starch and the fact that one of skill in the art would have tried different % (w/w) of starch to determine one that is suitable to obtain the desired granulate. The % (w/w) of starch is a matter of choice determined by what is found to be appropriate for the intended granulate. In the instant case, there is no evidence in the specification that shows that the amount of starch used to make the granulates affected phytase activity or pelleting stability in the granulate. With regard to the claimed composition, a person of ordinary skill in the art is motivated to add the *Aspergillus* phytase-containing granulate described above to an animal feed composition or to a composition where the feed is in the form of pellets because Nielsen et al. teach that the addition of phytases to an animal feed would (1) add nutritional value to the feed as it would liberate minerals bound in phytic acid complexes (page 2, lines 18-21), and (2) reduce the need to add inorganic phosphorous (page 2, lines 10-12).

One of ordinary skill in the art has a reasonable expectation of success at making an *Aspergillus* phytase-containing granulate using a carrier that comprises starch, wherein said granulate also comprises edible oil, gel-forming compounds, and endo-xylanases/ β -glucanases, since Ghani teaches the production of enzyme granules wherein the carrier is corn syrup solids, and starch-containing compounds such as corn flour, ground corn cobs, etc. as well as carriers covered with starch and granulates with gel-forming compounds, Nielsen et al. teach phytase granules comprising endo-xylanase/ β -glucanase, and Haarasilta and Nielsen et al. teach the use of extrusion for granulate manufacture. Furthermore, one of ordinary skill in the art has a reasonable expectation of success at making a phytase-containing granulate which further comprises an edible oil and a divalent cation since Haarasilta teaches fodder granules which contain soy oil and Ca^{2+} cations. Similarly, one of ordinary skill in the art has a reasonable expectation of success at making an edible animal feed composition comprising the *Aspergillus* phytase-containing granulate described above because Nielsen et al. teach a similar composition with their phytase-containing granulated feed additive. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

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Claims 18-19, 21, 24, 26-28, 31-35, 41-45, 48, 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996). The teachings of Nielsen et al., and Ghani have been disclosed above. Ghani also teaches that the granulates can have adjunct ingredients such as metallic salts (column 3, lines 14-25). Neither Nielsen et al. nor Ghani teach a divalent cation.

Claims 18, 45, 48, 50-52 are directed in part to an *Aspergillus* phytase-containing granulate comprising at least 6000 phytase units (FTU) per gram, wherein said granulate is prepared from an aqueous liquid comprising at least 14000 FTU per gram of aqueous liquid by extrusion, wherein said granulate contains a carrier comprising at least 15% (w/w) of starch, and wherein the granulate also comprises gel-forming compounds, an endo-xylanase, and a β -glucanase. Claims 19, 21, 24, 26-28 are directed in part to an *Aspergillus* phytase-containing granulate comprising at least 6000 phytase units (FTU) per gram, wherein said granulate is prepared from an aqueous liquid comprising at least 14000 FTU per gram of aqueous liquid, wherein said granulate contains a carrier comprising at least 15% (w/w) of starch, and wherein the granulate also comprises a divalent cation, gel-forming compounds, an endo-xylanase, and a β -glucanase. Claims 31-35, 41-44 are directed in part to a composition comprising the *Aspergillus* phytase-containing granulate described above with regard to claims 18-19, 21, 24, 26-28, 45, 48, 50-52, wherein said composition is an edible animal feed, or wherein the composition also comprises pellets that comprise one or more feed substances. Limitations regarding the method by which the granulate is made have been given little or no patentable weight for the reasons extensively discussed above. Similarly, limitations regarding pelleting stability are being considered inherent to a phytase-containing granulate for the reasons extensively discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make an *Aspergillus* phytase-containing granulate having at least 6000 FTU per gram which can be

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used as additive in animal feed, as taught by Nielsen et al., wherein the granulate is made using a carrier that comprises starch, as taught by Ghani, wherein said granulate is made using a phytase solution having a phytase concentration of more than 14000 FTU per gram of solution, and wherein said granulate further comprises (1) an endo-xylanase and/or β -glucanase as taught by Nielsen et al, (2) at least one divalent cation such as Zn^{2+} or Ca^{2+} , and/or (3) a gel-forming compound as taught by Ghani, wherein the granulate is made by extrusion, as taught by Nielsen et al. With regard to the claimed composition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the *Aspergillus* phytase-containing granulate described above to an animal feed composition or to the pelleted animal feed taught by Nielsen et al.

A person of ordinary skill in the art is motivated to (1) make an *Aspergillus* phytase-containing granulate using a carrier that contains, for example, corn syrup (non fibrous) and starch as well as a divalent cation such as Zn^{2+} or Ca^{2+} , for the benefit of adding nutritional value to the granulate and also due to the fact that phytases aid in the digestion of phytate-containing substances as taught by Nielsen et al. (page 2, lines 7-21), (2) use extrusion to prepare the granules as this method is well known and commonly used in industry for granulate manufacture, as evidenced by Nielsen et al., (3) add a gel-forming compound for the benefit of solidifying the granules and maintaining moisture and softness, and (4) add an endo-xylanase and/or β -glucanase since these are hydrolytic enzymes which would help in the digestion of complex carbohydrates which might be present in the feed, as taught by Nielsen et al. It is noted that Zn^{2+} and Ca^{2+} are well-known nutritional elements. With regard to the limitation requiring the carrier to have at least 15% (w/w) of starch, it is noted that the motivation to use a particular % (w/w) of starch derives from the teachings of Ghani regarding the use of starch and the fact that one of skill in the art would have tried different % (w/w) of starch to determine one that is suitable to obtain the desired granulate. The % (w/w) of starch is a matter of choice determined by what is found to be appropriate for the intended granulate. In the instant case, there is no evidence in the specification that shows that the

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amount of starch used to make the granulates affected phytase activity or pelleting in the granulate. With regard to the claimed composition, a person of ordinary skill in the art is motivated to add the *Aspergillus* phytase-containing granulate described above to an animal feed composition or to a composition where the feed is in the form of pellets because Nielsen et al. teach that the addition of phytases to an animal feed would (1) add nutritional value to the feed as it would liberate minerals bound in phytic acid complexes (page 2, lines 18-21), and (2) reduce the need to add inorganic phosphorous (page 2, lines 10-12).

One of ordinary skill in the art has a reasonable expectation of success at making an *Aspergillus* phytase-containing granulate using a carrier that comprises starch, wherein said granulate also comprises gel-forming compounds, and endo-xylanases/ β -glucanases, since Ghani teaches the production of enzyme granules wherein the carrier is corn syrup solids, and starch-containing compounds such as corn flour, ground corn cobs, etc. as well as carriers covered with starch and granulates with gel-forming compounds, Nielsen et al. teach phytase granules comprising endo-xylanase/ β -glucanase, and Nielsen et al. teach the use of extrusion for granulate manufacture. Furthermore, one of ordinary skill in the art has a reasonable expectation of success at making a phytase-containing granulate which further comprises Zn^{2+} and Ca^{2+} because Ghani teaches the use of additional elements such as metallic salts (e.g., Zn^{2+}) and the fact that compounds comprising these divalent cations are well-known and widely used as nutritional supplements. Similarly, one of ordinary skill in the art has a reasonable expectation of success at making an edible animal feed composition comprising the *Aspergillus* phytase-containing granulate described above because Nielsen et al. teach a similar composition with their phytase-containing granulated feed additive. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

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Claims 22, 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996) and further in view of Markussen et al. (U.S. Patent No. 4106991, 1978). The teachings of Nielsen et al. and Ghani have been discussed above. Neither Nielsen et al. nor Ghani teach granulates that contain polyvinyl alcohol.

Markussen et al. teach enzyme granules which contain polyvinyl alcohol (PVA) and/or cellulose derivatives such as carboxy-methyl cellulose (CMC; column 3, lines 9-18). Markussen et al. do not teach phytase-containing granulates.

Claim 22 is directed in part to an *Aspergillus* phytase-containing granulate comprising at least 6000 phytase units (FTU) per gram, wherein said granulate is prepared from an aqueous liquid comprising at least 14000 FTU per gram of aqueous liquid, wherein said granulate contains a carrier comprising at least 15% (w/w) of starch, and wherein the granulate also comprises a divalent cation, PVA, an endo-xylanase, and a β -glucanase. Claim 46 is directed in part to an *Aspergillus* phytase-containing granulate comprising at least 6000 phytase units (FTU) per gram, wherein said granulate is prepared from an aqueous liquid comprising at least 14000 FTU per gram of aqueous liquid by extrusion, wherein said granulate contains a carrier comprising at least 15% (w/w) of starch, and wherein the granulate also comprises PVA, an endo-xylanase, and a β -glucanase.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make an *Aspergillus* phytase-containing granulate having at least 6000 FTU per gram which can be used as additive in animal feed, as taught by Nielsen et al., wherein the granulate is made using a carrier that comprises starch, as taught by Ghani, wherein said granulate is made using a phytase solution having a phytase concentration of more than 14000 FTU per gram of solution, and wherein said granulate further comprises (1) an endo-xylanase and/or β -glucanase as taught by Nielsen et al, (2) at least one divalent

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cation, (3) polyvinyl alcohol (PVA) as taught by Markussen, and/or (4) a gel-forming compound as taught by Ghani, wherein the granulate is made by extrusion, as taught by Nielsen et al.

A person of ordinary skill in the art is motivated to (1) make an *Aspergillus* phytase-containing granulate using a carrier that contains, for example, corn syrup (non fibrous) and starch as well as a divalent cation such as Zn^{2+} or Ca^{2+} , for the benefit of adding nutritional value to the granulate and also due to the fact that phytases aid in the digestion of phytate-containing substances as taught by Nielsen et al. (page 2, lines 7-21), (2) use extrusion to prepare the granules as this method is well known and commonly used in industry for granulate manufacture, as evidenced by Nielsen et al., (3) add a gel-forming compound for the benefit of solidifying the granules and maintaining moisture and softness, (4) add PVA since this is one of several binders conventionally used in the art as taught by Markussen et al. (column 3, lines 9-13), and (5) add an endo-xylanase and/or β -glucanase since these are hydrolytic enzymes which would help in the digestion of complex carbohydrates which might be present in the feed, as taught by Nielsen et al. It is noted that Zn^{2+} and Ca^{2+} are well-known nutritional elements. As previously discussed, the motivation to use a particular % (w/w) of starch such as 15% derives from the teachings of Ghani regarding the use of starch and the fact that one of skill in the art would have tried different % (w/w) of starch to determine one that is suitable to obtain the desired granulate. As such, the % (w/w) of starch is a matter of choice determined by what is found to be appropriate for the intended granulate. In the instant case, there is no evidence in the specification that shows that the amount of starch used to make the granulates affected phytase activity or pelleting stability in the granulate, or pelleting stability of the granulate.

One of ordinary skill in the art has a reasonable expectation of success at making an *Aspergillus* phytase-containing granulate using a carrier that comprises starch, wherein said granulate also comprises PVA, gel-forming compounds, and endo-xylanases/ β -glucanases, since Ghani teaches the production of enzyme granules wherein the carrier is corn syrup solids, and starch-containing compounds such as corn

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flour, ground corn cobs, etc. as well as carriers covered with starch and granulates with gel-forming compounds, Markussen et al. teach the use of PVA as a binder for granulates, Nielsen et al. teach phytase granulates comprising endo-xylanase/ β -glucanase, and Nielsen et al. teach the use of extrusion for granulate manufacture. Furthermore, one of ordinary skill in the art has a reasonable expectation of success at making the phytase-containing granulate further comprising a divalent cation such as Zn^{2+} and Ca^{2+} because compounds comprising said cations are well-known and widely used as nutritional supplements and because Ghani teaches the use of additional elements such as metallic salts (e.g., Zn^{2+}) in his granulate. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

(10) Response to Argument

While appellant has presented separate arguments addressing the two independent claims and claims dependent therefrom, it is noted that many of these arguments are basically the same because claim 18 has essentially the same scope as that of claim 19 and their dependent claims have essentially the same wording. Claim 19 differs from claim 18 in that it requires the granulate to comprise a divalent cation and does not recite any limitation regarding the method of preparation (i.e., lacks the limitation "wherein said granulate is prepared by extrusion"). As such, the Examiner will address arguments that are applicable to both sets of claims only once, and will address those issues which are specific to each set of claims separately, if necessary.

A. Does the recitation of “increased pelleting stability” render claims 18 and 19 and the claims dependent therefrom indefinite and therefore unpatentable under 35 USC § 112, second paragraph?

On pages 4-7 of the brief, Appellant argues that the term “increased pelleting stability” refers to residual phytase activity and that the specification makes its abundantly clear to the ordinary skilled

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reader what is meant by the term, citing Examples 5 and 10 as evidence of how the term is used in the specification. Appellant also cites a declaration by Dr. Lutz End (hereinafter “End declaration”), who is an employee of the assignee of the instant application (BASF Aktiengesellschaft), filed on 1/24/2008 where it is stated that the term “increased pelleting stability” is intended to refer to residual phytase activity.

Appellant’s arguments have been fully considered. As indicated above, the ground of rejection related to the intended meaning of the term “pelleting stability” has been withdrawn.

On pages 7-9 of the brief, Appellant argues that relative terminology such as that recited in claims 18-19, i.e., “**increased** pelleting stability”, is permissible (emphasis added). Appellant submits that the Examiner has not made a determination as to whether the specification provides some standard for measuring that degree or whether one of skill in the art in view of the prior art would be reasonably apprised of the scope of the invention. It is appellant's contention that the specification provides a standard for measuring “pelleting stability” citing the findings provided in Examples 5 and 10 where the results of different pelleting experiments is provided. In those experiments, different pelleting conditions were tested and the phytase activity prior to and after pelleting were measured. Appellant further argues that even if one were to disregard the teachings of the specification as to how to measure “increased pelleting stability”, the prior art and the status of the art would reasonably apprise the skilled person on how to measure the increase. Appellant refers to the End declaration where it is stated that each enzyme has its own pattern of thermal inactivation and that any modification to the enzyme itself and/or the process of granulation that have a tendency to shift the stability curve to higher temperature tolerance would be understood to one of skill in the art to result in an “increased pelleting stability”. Furthermore, Appellant refers to Appeal No. 2006-0201 and states that the BPAI had no difficulty interpreting “pelleting stability” in a manner consistent with the arguments presented.

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Appellant's arguments have been fully considered but are not deemed persuasive to overcome the ground of rejection related to the term "increased". The Examiner acknowledges the teachings of Examples 5 and 10 and the reported results regarding how much residual phytase activity was left in granulates prepared under different conditions. The Examiner also acknowledges the End declaration. However the Examiner disagrees with Appellant's contention that the term is definite. The issue is not whether or not one could measure residual phytase activity after pelleting, or whether one could compare different results and determine **among the different results** which conditions appear to be less detrimental to phytase activity. The issue in the instant case is whether one could determine the standard for measuring the recited degree. That standard is variable and dependent upon the conditions used in the pelleting process. In all the examples provided, the determination as to whether one could see "increased pelleting stability" was based on **the comparison of one result with another**. For example, if under condition A as shown in Table 2 of the specification, the enzyme yield after pelleting is 17% when a granulate having 610 FTU/g is used, under condition B, the enzyme yield is 37% when a granulate having 4170 FTU/g is used, and under condition C, the enzyme yield is 48% when a granulate having 6830 FTU/g is used, one would observe "increased pelleting stability" with condition B when compared to condition A but one would not observe "increased pelleting stability" with condition B when compared to condition C. In other words, whether there is "increased pelleting stability" or not is solely dependent upon the reference used for comparison. Thus, contrary to appellant's assertion, the term is indefinite in the absence of standard for ascertaining the requisite degree.

With regard to arguments as to how the BPAI has interpreted the term "pelleting stability", it is noted that this is now moot in view of the withdrawal of the ground of rejection related to the intended meanings of the term "pelleting stability".

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B. Are claims 18-19, 21, 24, 26-28, 31-35, 41-44, 48, 50-52 unpatentable under 35 USC § 103(a) as being obvious over Nielsen et al. in view of Ghani?

On pages 10-12 of the brief, Appellant argues that the term “increased pelleting stability” should be given patentable weight. Appellant submits that the granulate of the invention overcomes stability problems arising from high temperatures used in pelleting for feed processing. According to Appellant, the term “increased pelleting stability” is definite for the reasons stated above. It is Appellant’s contention that once “increased pelleting stability” is given patentable weight, the rejection falls apart because none of the references cited address or discusses a connection between high phytase activity and increased pelleting stability, and Nielsen et al. do not teach extrusion. Appellant further argues that limitations have not been imported into the claims and that the Examiner’s interpretation relating to structural stability would not be reasonable in the context of the specification.

Appellant's arguments regarding an interpretation related to structural stability are now moot in view of the withdrawal of this ground of rejection. With regard to arguments that the term “increased pelleting stability” should be given patentable weight, it is noted that even if this term were to be found definite, **this limitation is inherent to a phytase-containing granulate that has a phytase activity indicated to be optimal for pelleting stability.** As repeatedly indicated by Appellant throughout the prosecution of the instant application, the End declaration, and the brief (see, for example, page 19, first full paragraph), the observed enhancement in pelleting stability is due to the use of a phytase-containing granulate that has a very high phytase activity. The specification of the instant application (page 13, lines 11-16) provides a range of 5000-10000 FTU/g of granulate for the phytase activity which is thought to be associated with an enhancement in pelleting stability, including 6000 FTU/g of granulate. Furthermore, Example 10 of the specification provides a working example where it is shown that there was a 6% increase in pelleting stability when the phytase activity of the granulate was increased from 4170 FTU/g to 6830 FTU/g (page 22, lines 24-29). Similarly, Example 5 of the specification discloses the highest

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pelleting stability when granulates having 6830 FTU/g granulate were used, compared to granulates having 4170 FTU/g or 610 FTU/g. There is absolutely no mention of the carrier or the process used to make the granulate as factors which influenced the observed increase in pelleting stability in Examples 5 or 10 of the specification. Moreover, as previously discussed, throughout the specification (page 8, lines 23-28; page 7, lines 7-22), the enhancement in pelleting stability is attributed solely to the use of a phytase-containing granulate which has a very high phytase activity. Thus, **based on the teachings of the specification and the arguments presented by Appellant throughout the entire prosecution of this application, neither the carrier used nor the method used to prepare the granulate appear to be factors influencing pelleting stability.** As such, if the art teaches a phytase-containing granulate having at least 6000 FTU/g and the specification discloses that a granulate having 6000 FTU/g has the desired "increased pelleting stability", then the granulate taught by the art would inherently have that desired property, regardless of the carrier or method used to prepare the granulates. **The mere presence of 6000 FTU/g of granulate is expected to be enough according to the specification and Appellant's arguments throughout the prosecution of the instant application for a phytase-containing granulate to display the desired pelleting stability.**

On pages 12-15 of the brief, Appellant argues that Nielsen et al do not teach or suggest the claimed granulate. Appellant submits that Nielsen et al. fail to teach the claimed granulate because (1) the calculation of phytase activity is based on total composition of a feed composition containing high amounts of proteinaceous vegetables whereas the claimed invention requires a phytase activity of 6000 FTU per gram of granulate, (2) while Nielsen et al. teach broad ranges that encompass the recited phytase activity, they do not teach the "6000 or more FTU/gram" species because there is no suggestion of its surprising properties of improved pelleting stability, (3) Example 3 as described by Nielsen et al. does not provide or suggest a granulate having at least 6000 FTU/gram but rather pellets without enzymes where the enzyme was added to the pellet after pelleting, thus the granulate of Nielsen et al. cannot have

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increased pelleting stability, and (4) the granulate in Example 3 as described by Nielsen et al. would only have a phytase activity of 1.496 FYT/g of feed, which is well below the 6000 FTU/g required by the claims. Appellant further argues that there is nothing taught by Nielsen et al. which would lead one of skill in the art to select a particular phytase activity of the granulate from the broad ranges taught. Appellant cites case law in support of the argument that the Examiner cannot selectively pick and choose from the disclosed parameters without proper motivation.

Appellant's arguments have been fully considered but are not deemed persuasive to overcome the instant rejection. Appellant's conclusion that the phytase activity ranges provided by Nielsen et al. are based on total composition of a feed composition appears to be in error. As stated by Nielsen et al. on page 10, lines 8-24,

“In the context of this invention, an animal feed additive is an enzyme preparation comprising one or more phytase enzymes and one or more proteolytic enzymes and suitable carriers and/or excipients, and which enzyme preparation is provided in a form that is suitable for being added to animal feed. The animal feed additive of the invention may be prepared in accordance with methods known in the art and may be in the form of a dry or a liquid preparation. The enzyme to be included in the preparation, may optionally be stabilized in accordance with methods known in the art.

In a specific embodiment the **animal feed additive of the invention is a granulate enzyme product which may readily be mixed with feed components**, or more preferably, form a component of a pre-mix. The granulated enzyme product may be coated or uncoated. The particle size of the enzyme granulates preferably is compatible with that of feed and pre-mix components. This provides a safe and convenient mean of incorporating the enzymes into feeds.”
(emphasis added)

Furthermore, Nielsen et al. states on page 11, line 27 through page 12, line 5,

“It is at present contemplated that the amount of phytase activity in the animal feed additive should be in the range of from 200 to about 50000 FYT (as defined below) per gram of total composition, preferably in the range of from about 500 to about 10000 FYT per gram of total composition, most preferred in the range of from about 2000 to about 6000 FYT per gram of total composition.

Preferably, the amount of additive added to the animal feed should be sufficient to provide a feed composition containing at least 50 FYT per kg feed, more preferably, between about 100 and about 2000 FYT per kg feed.” (emphasis added)

From these statements, it is abundantly clear that (1) **the animal feed additive being referred to by Nielsen et al. is a granulate that has phytase activity**, (2) **the granulated animal feed additive is not required to have proteinaceous vegetables**, (3) **the granulated animal feed additive is not required to be the same as a feed composition or an animal feed comprising a phytase**, (4) **the recited phytase activities for the granulate (animal feed additive) of Nielsen et al. are based on grams of total composition of the additive (granulate) and not based on grams of total feed composition** as asserted by Appellant, and (5) Nielsen et al. teach a granulate having **specifically 6000 FTU/g granulate** as well as granulates having more than 6000 FTU/g granulate, which is what is required by the claims.

If Nielsen et al. refer to “the amount of phytase activity **in the animal feed additive** (granulate) should be in the range of from 200 to about 50000 FYT per gram of total composition”, how could the amount of phytase activity in the additive be calculated on the basis of a feed composition and not the

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granulate itself? Even if the granulate were to contain high amounts of proteinaceous vegetables as well as other components, the total composition indicated by Nielsen et al. must be the total granulate composition, which would include everything that is in the granulate. Any other interpretation of the term “total composition” beyond “total granulate composition” would be **illogical**. Thus, contrary to Appellant’s assertions, (1) the phytase activities in the granulates of Nielsen et al. are based on grams of granulate and not grams of a feed composition comprising high amounts of proteinaceous vegetables as asserted by Appellant, and (2) Nielsen et al. teach not only granulates having phytase activities higher than 6000 FTU/g granulate, but they specifically teach a granulate having a phytase activity of 6000 FTU/g granulate, thus meeting the numerical phytase activity limitation recited in the claims. With regard to the argument that the granulate of Nielsen et al. does not have the recited “improved pelleting stability”, as indicated above, even if this term is deemed definite, that limitation is inherent to a phytase-containing granulate having at least 6000 FTU/g granulate. See extensive discussion above as to the reasons why the Examiner has reached the conclusion that such limitation is inherent to the granulate of Nielsen et al. With regard to Example 3 as disclosed by Nielsen et al., it is noted that the Examiner never contended that Example 3 provides a granulate that has 6000 FTU/g of granulate, nor has the Examiner ever relied on Example 3 to show that Nielsen et al. teach a granulate that has at least 6000 FTU/g of granulate. Thus, while the Examiner acknowledges that the granulate of Example 3 would not meet the 6000 FTU/g granulate limitation, **arguments regarding Example 3 are deemed irrelevant to the instant rejection as the disclosure of Example 3 has never been indicated by the Examiner as the teaching of Nielsen et al. which renders the claimed invention obvious over the prior art.**

On pages 15-18 of the brief, Appellant argues that the Examiner has not made clear that the missing feature of “increased pelleting stability” is necessarily present in the additives taught by Nielsen et al. According to Appellant, Nielsen et al. do not disclose a granulate having at least 6000 FTU/g granulate, and because the enzyme is added to an already pelleted animal feed, the Examiner has not

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established that the reference teaches a product appearing to be substantially identical to the claimed product, let alone that the missing “increased pelleting stability” limitation is necessarily present in the granulate taught by Nielsen et al. to show inherency. Appellant states that the claimed invention is a granulate not a pellet and that Example 3 of Nielsen et al. teach that the phytase was added to a pellet after pelleting, thus cannot have increased pelleting stability, whereas for the present phytase-containing granulate to have increased pelleting stability as claimed, the phytase is added prior to pelleting.

Appellant further cites *In re Antonie* and asserts that the facts in this case are similar to those in *In re Antonie* in that Nielsen et al. do not teach a specific example of a granulate and do not disclose anything that would lead one to identify that granulates with at least 6000 FTU/g would improve pelleting stability.

For the reasons extensively discussed above, **Nielsen et al. teach a granulate having at least 6000 FTU/g of granulate and not 6000 FTU/g of animal feed composition as asserted by appellant.** In addition, as previously discussed, Example 3 has never been indicated by the Examiner as teaching a granulate comprising at least 6000 FTU/g granulate and is **irrelevant** to the instant discussion. As previously stated, the term “improved pelleting stability”, even if found definite, is a limitation which is inherent to the granulate of Nielsen et al. It is reiterated herein that the specification, appellant's arguments throughout the prosecution of the instant application, the End declaration, and appellant's argument in the brief (see, for example, page 19, first full paragraph) have made it abundantly clear that it is the high level of phytase activity in the granulate what is believed to be the reason why there was an enhancement in pelleting stability. Neither the use of starch or how much starch is used, nor the method by which the granulate is made have been taught or suggested in the specification as being either direct or indirect factors influencing pelleting stability. See extensive discussion above as to why the specification is not believed to teach or suggest starch or extrusion as factors which would influence pelleting stability presented under the “Grounds of Rejection” section. As such, the logical conclusion for one of skill in the art to make is that, in the absence of evidence to the contrary, any phytase-containing granulate that

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has at least 6000 FTU/g of granulate would also have enhanced pelleting stability compared to a phytase-containing granulate that has, for example, 610 FTU/g of granulate (sample A in Example 5 of the specification, Table 2). **It is Appellant's own specification and arguments in previous responses and brief which support the Examiner's position that the recited "increased pelleting stability" limitation is inherent to the phytase-containing granulate of Nielsen et al.** Therefore, none of the cited references, including Nielsen et al. is required to teach "increased pelleting stability", or teach/suggest the relationship between pelleting stability and the level of phytase activity in the granulate.

Arguments regarding the similarities between the instant case and the facts in *In re Antonie* are not found persuasive because in the instant case, while it is agreed that none of the references teach "increased pelleting stability", **the Examiner has never argued that the "increased pelleting stability" is obvious or that one of skill in the art would be motivated to make a granulate having that limitation.** Instead, the Examiner has simply argued that **the limitation would be inherent to the granulate of Nielsen et al. alone** in view of Appellant's own statements throughout the prosecution of the instant application and the teachings of the specification regarding how pelleting stability is affected by the level of phytase activity in the granulate, as well as the absence of any teaching or suggestion by Appellant or the specification that the carrier used or the granulate's method of manufacture are direct or indirect factors which also influence pelleting stability.

On pages 18-19 and 21 of the brief, Appellant argues that Ghani does not teach or suggest a non-fibrous solid carrier which comprises at least 15% (w/w) of starch, pelleting stability with regard to phytase granulates, divalent cations, or granules prepared by extrusion. Appellant argues that Ghani teaches gentler preparation methods. Therefore, Ghani does not cure the deficiencies of Nielsen et al. Furthermore, Appellant argues that these references do not teach, suggest or recognize that increased pelleting stability is a function of the high activity phytase-containing granulate as claimed. Appellant submits that the highly concentrated granulate overcomes enzyme stability problems arising from high

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temperatures associated with pelleting during feed processing while retaining high enzyme activity, which is evidence that the claimed invention possesses unexpectedly advantageous or superior properties.

Appellant's arguments have been fully considered but are not deemed persuasive. As previously stated, the "non-fibrous" limitation recited in claims 18 and 19 cannot be interpreted as "lacking fiber" in view of the fact that the carrier is required to have at least 15% (w/w) of starch which known in the art to contain dietary fiber. See above for a copy of the table provided with the Advisory action mailed on 8/15/2006, where it is shown that starch contains dietary fiber (see item 13 of the PTO-303 form submitted with that action). A carrier containing starch cannot be a carrier that completely lacks fiber, i.e., non fibrous. It is noted that the working examples provided by Appellant in the specification use starch, including cornstarch, thus even in light of the specification, one cannot reasonably conclude that the term "non-fibrous" as used in the claims was intended to mean "lacking fiber".

With regard to the limitation requiring the carrier to have at least 15% (w/w) of starch, as previously stated, Ghani teach the use and advantages of starch in combination with many solid carriers including non-fibrous carriers such as corn syrup solids and starch-containing carriers such as corn flour. As indicated above, Ghani discloses a carrier comprising corn syrup with soy flour, which is further coated with Miragel 463 (hydrolyzed starch) (column 6, lines 43-50, Example 5). Furthermore, one of skill in the art would be motivated to add starch to the carrier since starch would add nutritional value to the granulate. Also, the use of a specific % (w/w) of starch is dependent upon how much starch is desired in the granulate and how much starch is suitable for a particular application. In addition, there is no evidence in the specification, nor has it ever been argued by Appellant, that how much starch is used to make the granulates is a factor in how much phytase activity is lost during the pelleting process (pelleting stability). The absence of a correlation between starch and pelleting stability is also evidenced by the fact that the % (w/w) of starch used in Example 5 for samples A, B and C is approximately 70% (w/w) in all samples (73%, 70%, and 67%, respectively), whereas the residual phytase activity, reported as enzyme

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yield after pelleting, is < 17%, 37% and 48%, respectively (Table 2). As such, one of skill in the art would reasonably conclude that the specification does not teach or suggest a correlation between how much starch is used and pelleting stability. Thus, the “non-fibrous solid carrier comprising at least 15% (w/w) of starch” limitation is deemed obvious over the teachings of Ghani as previously discussed.

With regard to divalent cations, while the Examiner recognizes that neither Nielsen et al. nor Ghani teach a divalent cation specifically, it should be noted that (1) Ghani, as previously stated, teaches the use of metallic salts, (2) the addition of a compound that would provide Ca^{2+} and/or Zn^{2+} (metallic salt) to a granulate which is intended to be used with a feed composition would be obvious in view of the fact that Ca and Zn are well known nutritional elements which are commonly added to nutritional supplements, and (3) there is no teaching or suggestion in the specification or the prior art that the presence or absence of these divalent cations would have any effect on pelleting stability. The Examiner also recognizes that neither Nielsen et al. nor Ghani teach pelleting stability or extrusion as a method to make enzyme granulates. However, it is noted that (1) extrusion is a limitation related to the process of manufacture of the claimed product and the patentability of a product recited in **product-by-process** format is determined only by the characteristics of the product (MPEP § 2113), (2) Nielsen et al. teach extrusion with regard to feed compositions (page 10, lines 25-26), (3) **extrusion is one of the most common methods to make granules as admitted by Appellant in the specification** (page 8, lines 23-28), and (4) the specification as previously discussed under the "Grounds of Rejection" section, teaches that any mechanical process known in the art to make granulates can be used to make the granulates of the invention (page 8, lines 23-28), thus **essentially teaching that extrusion is not a factor affecting “pelleting stability”**. Since pelleting stability does not appear to be a function of either divalent cations or the mechanical technique used to manufacture the granulate, limitations requiring divalent cations and extrusion as the manufacture's method are deemed not related to the “increased pelleting stability” limitation. Thus, in view of the teachings of the specification and Appellant's own statements, the

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granulate of Nielsen et al. **alone** would inherently have the required pelleting stability because it contains the only characteristic that Appellant has continuously indicated as the characteristic which would allow a phytase-containing granulate to have the desired pelleting stability, i.e., at least 6000 FTU/g of granulate. Therefore, contrary to Appellant's assertions, none of the cited references is required to teach pelleting stability or a correlation between phytase activity and pelleting stability.

With regard to arguments that the highly concentrated granulate overcomes enzyme stability problems arising from high temperatures associated with pelleting during feed processing while retaining high enzyme activity, it is noted that this assertion further supports the Examiner's position that the only characteristic disclosed by the specification and appellant as the determining factor in observing an enhancement in pelleting stability is the level of phytase activity in the granulate. Therefore, while the Examiner acknowledges Appellant's findings regarding the observed increase in pelleting stability when phytase-containing granulates have high phytase activity levels, these unexpectedly advantageous or superior properties are properties which are inherent to any phytase-containing granulate comprising at least 6000 FTU/g of granulate based on the teachings of the specification and Appellant's own arguments.

Therefore, for the reasons extensively discussed above, the claimed invention is deemed obvious over the teachings of Nielsen et al. and Ghani.

C. Are claims 22 and 46 unpatentable under 35 USC § 103(a) as being obvious over Nielsen et al. in view of Ghani and further in view of Markussen et al.?

On pages 23-24 of the brief, Appellant argues that while the Examiner relied on Markussen et al. for allegedly teaching an enzyme granulate that contains polyvinyl alcohol (PVA), the disclosure of Markussen et al. is limited to granulates requiring a fibrous carrier (cellulose). Appellant contends that one of skill in the art would not look to the teachings of Markussen et al. for a granulate as claimed because Markussen et al. teach granulates comprising a fibrous carrier. Furthermore, Appellant argues

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that the combined teachings of Nielsen et al., Markussen et al. and Ghani would not arrive at the claimed granulate because neither Nielsen et al. nor Ghani provide a granulate having "increased pelleting stability" and at least 6000 FTU/g granulate and a non-fibrous carrier. In addition, it is appellant's contention that none of these references teach, suggest or recognize that increased pelleting stability is a function of the high activity phytase-containing granulate as recited.

Appellant's arguments have been fully considered but are not deemed persuasive. The Examiner acknowledges that Markussen et al. disclose granulates comprising cellulose. However, Markussen et al. teach PVA as well as other compounds as binders which are conventionally used in the field of granulation (column 3, lines 9-13). Markussen et al. do not teach that PVA is a binder which should only be used with fiber-containing carriers. Instead, Markussen et al. make it abundantly clear that PVA along with other compounds, is a commonly used binder. As such, one of skill in the art would reasonably conclude that any of the binders taught as conventionally used in the field of granulation can potentially be used to make a granulate. Therefore, contrary to Appellant's assertions, one of skill in the art would look to the teachings of Markussen et al. because **Markussen et al. specifically teach that PVA is conventional in the art, regardless of the nature of the carrier.** Arguments regarding Nielsen et al. and Ghani as not teaching or suggesting (1) a phytase-containing granulate having a phytase activity of 6000 FTU/g granulate, or (2) increased pelleting stability as a function of the high activity phytase-containing granulate as recited, have already been addressed by the Examiner above. Markussen et al. is also not required to teach or suggest increased pelleting stability as a function of the high activity phytase-containing granulate as recited because the granulate of Nielsen et al. **alone** inherently has the recited "increased pelleting stability" limitation recited in the claims. Therefore, for the reasons extensively discussed above, the claimed invention is deemed obvious over the teachings of Nielsen et al., Ghani and Markussen et al.

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D. Are claims 18-19, 21-22, 24, 26-28, 31-35, 41-46, 48, 50-52 unpatentable under 35 USC § 103(a) as being obvious over Nielsen et al. in view of Ghani and further in view of Haarasilta?

On pages 27-29 of the brief, Appellant submits that the purpose of the inorganic salts in the feedstuff of Haarasilta is to assist in the formation of stable granulates which are resistant to decomposition in rumen conditions. Appellant argues that one of skill in the art would not look to the disclosure of Haarasilta to make a granulate as claimed because the teachings of Haarasilta are related to a granulate that is resistant to highly acidic conditions and comprises fibrous materials (hay or straw), whereas the claimed granulate has a non-fibrous carrier and can withstand high temperatures associated with the pelleting process. In addition, Appellant submits that none of the cited references teach, suggest or recognize that increased pelleting stability is a function of the high activity phytase-containing granulate as claimed.

Appellant's arguments have been fully considered but are not deemed persuasive. The Examiner acknowledges that Haarasilta adds the inorganic salts to granulates which are resistant to decomposition in rumen conditions. However, the Examiner disagrees with Appellant's contention that one of skill in the art would not look to the disclosure of Haarasilta to make a granulate as claimed because the granulate of Haarasilta contains fibrous materials and is intended to be given to cattle. On the contrary, one of skill in the art would be highly motivated to look to the disclosure of Haarasilta simply because **the granulate of Nielsen et al. is an animal feed additive** (see the teachings of Nielsen et al. on page 10, lines 8-24 reproduced above). As such, **cattle would be a target for the animal feed additive of Nielsen et al.** Therefore, while it is agreed that one of skill in the art would not add the inorganic salts of Haarasilta to increase pelleting stability, one of skill in the art would be highly motivated to add the inorganic salts of Haarasilta to the granulate of Nielsen et al. to make the granulate more resistant to decomposition in cattle's rumen. With regard to arguments that one of skill in the art would not consider the teachings of

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Haarasilta because the granulates of Haarasilta contain fibrous materials, it is noted that (1) nowhere in Haarasilta or the prior art, there is any teaching or suggestion that only granulates which contain fibrous materials can be made more resistant to decomposition in rumen conditions by adding inorganic salts, and (2) the claimed granulates contain fiber as extensively discussed in the “Grounds of Rejection ” section. Furthermore, one of skill in the art would easily recognize that the addition of Ca to the granulate of Nielsen et al. would not only provide a granulate which can be more resistant to decomposition in rumen conditions, but would also provide a granulate with added nutritional value since Ca is a well-known nutritional supplement.

Arguments regarding Nielsen et al. and Ghani as not teaching or suggesting (1) a phytase-containing granulate having a phytase activity of 6000 FTU/g granulate, or (2) increased pelleting stability as a function of the high activity phytase-containing granulate as recited, have already been addressed by the Examiner above. Haarasilta is also not required to teach or suggest increased pelleting stability as a function of the high activity phytase-containing granulate as recited because the granulate of Nielsen et al. **alone** inherently has the recited “increased pelleting stability” limitation recited in the claims. Therefore, for the reasons extensively discussed above, the claimed invention is deemed obvious over the teachings of Nielsen et al., Ghani and Haarasilta.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Delia M. Ramirez/

Primary Examiner, Art Unit 1652

Conferees:

/Manjunath N. Rao /

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/Andrew Wang/

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